

Attorney Docket No.: 2870/192

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of: Lawson, et al.

Serial No.: 09/441,832

Group Art Unit: 1619

Filed: November 17, 1999

Examiner: Berman, Alysia

For: Gel-Type Oil Free Cosmetic

RESPONSE PURSUANT TO 37 CFR 1.116

The Assistant Commissioner of Patents and Trademarks

Washington, D.C. 20231

Dear Sir:

In the Examiner's Final Office Action, dated August 21, 2001, Claims 1 to 3, 7 to 19, 21, 23, 25, and 26 remain rejected. Applicants thank the Examiner for the phone interview of August 15, 2001 which is summarized in the Examiner's Interview Summary. Please consider the following remarks clarifying why Applicants were not able adopt the Examiner's suggestion and guidance regarding the limitations that could be made to the independent claims of the present invention to render them in condition for allowance.

I. Definition of Sterol-Based Surfactant/Emulsifier:

The Examiner alleges that Claims 1 to 3, 7, 9 to 19, 23, 25 and 26 fail to particularly point out and distinctly claim the subject matter of the present invention. In response to Applicants' previous arguments, the Examiner states that a "fair review of the present specification, at page 4, did not reveal an exclusive definition of sterol-based surfactants." Further, the Examiner is of the opinion that the definition in the present specification supports the indefiniteness of the term because it does not further define the derivatives recited therein. Applicants are not aware of any requirement under §112 that a definition must be "exclusive," and the indefiniteness provisions of §112 do not require an applicant to describe each and every detail of the subject matter claimed. As there is only one definition, it is not clear why it is not exclusive. It is well established that under §112, subject matter is sufficiently described when a person of ordinary skill in the art is able to recognize that what is claimed has been invented. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1556-58, 220 USPQ 303, 315-16 (Fed. Cir. 1983)(emphasis added)(claims not indefinite because the evidence showed that those skilled in the art understood their scope even though the specification failed to disclose precise definitions); *Union Oil Co.*

of *California v. Atlantic Richfield Co.*, 54 USPQ2d 1227, 1232 (CAFC 2000)(citations omitted). It is also recognized that the claims may use language that those skilled in the art understand without the need for explicit, detailed definitions in the written description. *Id.* (emphasis added).

The present specification, at page 4, defines "sterol-based surfactant or emulsifier" as follows, "[u]seful sterol-based surfactant/emulsifiers include cholesterol and phytosterols, or derivatives thereof." What is presently at issue is that the definition is not "exclusive" and that derivatives are not described. Applicants are uncertain as to what is meant by exclusivity, and why or how this affects patentability. However, the fact that the definition does not expressly state, for example, "sterol-based surfactant/emulsifiers are defined to be . . . " should not prevent one of ordinary skill in the art from understanding the metes and bounds of this well-known term of art. Therefore, the claims are believed to meet the requirements of 35 U.S.C. §112, second paragraph, and, Applicants request that this rejection be withdrawn.

II. Novelty:

Claims 1, 2, 7 to 11, and 14 remain rejected under 35 U.S.C. §102(b) as being anticipated by McEleney et al. (U.S. Pat. No. 5,567,420, hereinafter referred to as "the '420 reference") and separately, the same claims are rejected as being anticipated by Tominaga (U.S. Pat. No. 5,747,049, "the '049 reference"). Applicants previously in their Response of July 13, 2001 ("Applicants' Previous Response"), pointed out that the components of the non-emulsion gel of the present invention as they are arranged in the claims are not disclosed by either of the cited references. Anticipation requires "the presence in a single prior art disclosure of all elements of a claimed invention arranged as in that claim." *Carella v. Starlight Archery*, 231 USPQ 644, 646 (CAFC 1986)(emphasis added). Therefore, one of ordinary skill in the art would not be able to make a non-emulsion gel based on the disclosure of the '049 reference or the '420 reference because neither reference describes the elements in relation with one another to make a non-emulsion gel.

The present invention is a non-emulsion gel-type composition which is not disclosed by either of the cited references. Specifically, as set forth in the present specification at page 2, lines 27 to 28, the base of the composition is a polyhydric alcohol gelled by an amine or an alkali metal salt of a fatty acid ester, and the other component of the composition is a carbohydrate-based or sterol-based surfactant/emulsifier. The non-emulsion gel compositions of the present invention contain substantially no oil and are novel because the '049 and the '420 references each fails to disclose these compositions.

A. The '420 Reference:

The Examiner asserts that the '420 reference discloses all of the limitations of the present invention, and that one of ordinary skill in the art would understand from the teachings of the '420 reference that the compositions may be in the form of emulsions or gels. However, the '420 reference discloses just the opposite. The specific types of gels that are suitable for the alleged invention in the '420 reference are found at column 3, lines 34 to 38, and states the following.

For topical use, it is desirable that a CI [color indicator] is dispersed in an emulsion of sunscreen or lotion and applied to the skin. For this purpose, the CIs are intended to be admixed in a pharmacologically acceptable topical carrier such as a gel . . .

Thus, contrary to the Examiner's assertion, the '420 reference discloses that its gels are emulsions, and one of ordinary skill in the art based on the disclosure of the '420 reference would understand that the gels of the '420 reference are emulsions. Therefore, the '420 reference fails to disclose a non-emulsion gel.

B. The '049 Reference:

The Examiner points out that the '049 reference discloses gels separately from water-oil two phase systems, i.e., emulsions, and that it discloses the other elements of the present claims. However, the '049 reference fails to disclose the components of the non-emulsion gels of the present invention as they are arranged in the claims. The standard for anticipation requires the presence in a single prior art disclosure of all elements of a claimed invention arranged as in the claim. A prior art disclosure that "almost" meets the standard does not "anticipate." *Structural Rubber Products Co. v. Park Rubber Co. et al.*, 223 USPQ 1264, 1271 (CAFC 1984)(citing *Sound-scriber Corp. v. U.S.*, 360 F.2d 954, 960, 148 USPQ 298, 301 (Ct. Cl. 1966)). The '049 reference discloses a method of using aminoethyl containing compositions. The laundry list of bases or vehicles disclosed in the '049 reference, for use in its compositions, is insufficient as a disclosure of the present invention because one of ordinary skill in the art would not reasonably be able to ascertain a particular combination of bases or vehicles from the multitude of combinations disclosed in the '049 reference to make a non-emulsion gel of the present invention. Therefore, the '420 reference fails to disclose a non-emulsion gel with substantially no oil and the other components, as described in the claims of the present invention, and therefore, fails to meet the standard for anticipation. As both of the cited references fail to disclose the present invention, Applicants request that the rejections based on 35 U.S.C. §102(b) be withdrawn.

III. Non-Obviousness:

In the present Office Action, Claims 1, 2, 7 to 11, 14 to 17, 21, 23, and 25 remain rejected under 35 U.S.C. §103 as being unpatentable over either U.S. Patent No. 5,567,420 issued to McEleney et al. ("the '420 reference") or U.S. Patent No. 5,747,049 issued to Tominaga ("the '049 reference"). The Examiner notes that although they each do not teach the amounts of the components as claimed in Claims 15 and 16, the ability to select optimal amounts is within the skill of the art. As indicated, above with respect to the §102 rejections, each of the cited references not only fails to teach the amounts, but also, fails to teach the non-emulsion gel of the present invention. The '049 aminoethyl containing compositions can be in the form of a gel, as taught at column 7, line 38, after which a lengthy list (spanning over several columns) is provided of known bases or vehicles that can be used in the '049 compositions. However, the '049 reference is devoid of any teaching or suggestion, except for the examples, of how any of these bases or vehicles are to be combined let alone how they could be combined to achieve a mousse-like non-emulsion gel of the present invention. If a single reference could simply comprise a long laundry list of everything that exists in the world that could potentially be used in a composition, the fundamental purpose of encouraging inventiveness and the advancement of science by means of a patent system would be belied because that single reference would destroy the patentability of any invention. This is simply not the founding principle of patentability rules.

As pointed out in Applicants' Previous Response, any invention can consist of a combination of old elements, but it is the claimed combination that must be found obvious to render the invention unpatentable. *The Gillette Co. v. S.C. Johnson & Son Inc.*, 16 USPQ2d 1923, 1927 (CAFC 1990). The critical inquiry is whether "there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination." *The Gillette Co. v. S.C. Johnson & Son Inc.*, 12 USPQ2d 1929, 1945 (DC Mass) (citing *Lindemann Maschinenfabrik v. American Hoist & Derrick*, 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir., 1984)). In the absence of the claimed invention from the prior art, if there is simply no basis upon which to predicate what seems to be the most unlikely combination in the prior art, obviousness is not found. *In re Schoenewaldt*, 145 USPQ 289, 292 (CCPA 1965) (references including a shot gun disclosure fail to give any indication of either the utility or the properties of the claimed compound except as properties were attributable to them by hindsight).

The present invention is a substantially oil-free non-emulsion gel with excellent moisturizing properties. The mousse-like non-emulsion gels comprise an aliphatic polyhydric alcohol, a gelling agent

of an alkali salt or an amine salt of a fatty acid, a surfactant/emulsifier, and water. It is not necessary for the claims of the present invention to recite that the gel is "mousse-like" because the claims already recite features of the gel, namely, its non-emulsion form and the relationship of the components to make the non-emulsion gel, that are not taught or suggested by the '049 reference. The '049 reference merely suggests the critical components of the invention in isolation and without teaching any relationship among them. At best, based on the examples provided at column 14, line 60, FORMULATION EXAMPLE 1, to column 18, line 28, FORMULATION EXAMPLE 7, the '049 reference teaches, in each example, that the likely combination of any of the bases or vehicles is in an emulsion system as each example has an oil phase and an aqueous phase. Therefore, the '049 reference fails to teach a non-emulsion gel containing the components of the present invention, *per se*, and it certainly fails to teach or suggest to one of ordinary skill in the art that there is any relationship among its run-on list of bases or vehicles to make a non-emulsion gel. If the prior art does not indicate a relationship among the components or that a relationship is well known in the art, and if it does not suggest the claimed relationship, obviousness is not found. *In re Rijckaert*, 28 USPQ2d 1955, 1957 (CAFC 1993)(citing *In re Yates*, 663 F.2d 1054, 211 USPQ 1149, 1151 (CCPA 1981) (PTO must indicate where such a teaching or suggestion appears in the reference)). The '049 reference lacks any teaching, suggestion or motivation to combine any of the bases or vehicles in a non-emulsion gel or any particular way, other than in an emulsion system. Therefore, because none of the cited references discloses a non-emulsion gel of the present invention, a *prima facie* case of obviousness has not been made.

In rejecting claims under 35 U.S.C. §103, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness. *In re Rijckaert*, 28 USPQ2d 1955, 1956 (CAFC 1993) (citing *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant. *Id.* "A *prima facie* case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." *Id.*, (citing *In re Bell*, 991 F.2d 781, 782, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993) (quoting *In re Rinehart*, 531 F.2d 1048, 1051, 189 USPQ 143, 147 (CCPA 1976)). Since a *prima facie* case of obviousness has not been made, for reasons which are discussed above, the burden of coming forward with evidence or data regarding unexpected properties has not shifted to Applicants. Previously, for argument's sake, Applicants pointed out that even if a *prima facie* case of obviousness could be made, it is rebutted by the unexpected properties of the present invention, i.e., showing that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected."

In re Geisler, 43 USPQ2d 1362, 1365 (CAFC 1997); see *In re Soni*, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995). The present invention is a non-emulsion gel which is unexpectedly moisturizing and feels cool, even though it contains substantially no oil. This unexpected benefit of the present invention is not recognized by the cited references.

Finally, Applicants address three additional references cited by the Examiner, U.S. Patent No. 5,424,070 ("the '070 reference"), U.S. Patent No. 5,741,499 ("the '499 reference"), and the U.S. Patent No. 5,393,526. First, the Examiner, in error, asserts that sodium behenate taught in the '070 reference can be substituted for sodium stearate in either the '420 reference or the '049 reference as the '070 reference discloses that these two compounds are equivalent and one would expect similar results from the substitution. The Examiner fails to point out where in the '070 reference such a disclosure is made. However, upon review of the '070 reference, it can be seen that this disclosure is not made in the '070 reference. The '070 reference teaches a combination of 5 different fatty acid soaps including sodium stearate and sodium behenate, *inter alia*, as a gel-forming agent. This is not a teaching or suggestion that the two fatty acid soaps are capable of being substituted for one another in the '070 compositions or any other composition for that matter. Therefore, as discussed in Applicants' Previous Response, the '070 reference fails to teach or suggest that such a substitution can be made.

Second, in response to Applicants' previous argument that the '499 reference teaches away from the present invention, the Examiner mentions that the '499 reference demonstrates that it is known in the art to use isoprene glycol and silicone coated pigments in a topical mousse composition. Similarly, the Examiner notes that the '526 reference shows that it is known in the art to use dimethicone coated pigments in cosmetics. However, Applicants believe that these demonstrations have no bearing on the underlying issue of patentability, and specifically, the issue non-obviousness when the '420 reference and the '049 reference each fail to teach or suggest the present invention.

The present invention is a non-emulsion gel composition comprising an aliphatic polyhydric alcohol, an alkali salt of a fatty acid ester, a carbohydrate-based or sterol-based surfactant/emulsifier or combination thereof, water and substantially no oil. The gels of the '420 reference are emulsions, and thus, the '420 reference fails to teach or suggest the non-emulsion gels of the present invention. The '049 reference provides a long laundry list of bases or vehicles that can be used in its aminoethyl containing compositions. However, there is no teaching or suggestion in the '049 reference as to how any of the vast number of individual bases or vehicles can be combined to make a non-emulsion gel, and

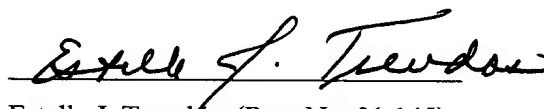
therefore, it also fails to render the present invention obvious. The only thing that one of ordinary skill in the art could possibly surmise from the teachings or suggestions of the '049 reference with respect to a common thread among the many bases or vehicles is that they each are likely to be used in an emulsion, based on the examples provided therein. This is hardly a teaching or suggestion of how to make a non-emulsion gel that has surprising moisturization qualities. Neither the '420 reference nor the '049 reference places the non-emulsion gels of the present invention in the possession of one of ordinary skill in the art. Therefore, these references, alone or in combination with any of the other cited references, i.e., the '526 reference, the '499 reference and the '070, fail to teach or suggest the present invention. Applicants request that the §103 rejections be withdrawn.

CONCLUSION

Applicants gratefully acknowledge the Examiner's guidance in adding the limitations of Claims 3, 8, 9 and 13 to the independent claims as a way of placing the application in condition for allowance. However, Applicants believe, based on the arguments presented above in the present submission, that the present claims are in condition for allowance, and therefore, a Notice of Allowance for the present claims is respectfully solicited.

Respectfully submitted,

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